

additional protective layer .... is preferably inserted between the core and the water-insoluble, permeable coating.” Applicants respectfully submit claim 13 and 14 are patentable under 35 USC 112, first paragraph and respectfully request withdrawal of the rejection.

**Rejection under 35 USC § 112, second paragraph**

The Examiner rejected claims 32 - 37 under 35 USC § 112, second paragraph for indefiniteness. The claims recite “...prevention of migraine recurrence...” The meaning of the word prevent was deemed unclear by the Examiner. The Examiner asserts that “the word prevent implies a cure.” The Examiner further states that as there is no cure for migraines recurrence, the term “treatment” would be more correct. Applicants submit that the meaning and scope of the term “prevention of migraine recurrence” recited in the claims is clearly defined when taken in the context of the definition of the term “migraine recurrence” given on page 1, lines 18 - 21 of the instant specification where it is stated “Migraine recurrence is a separate condition from migraine itself and can be defined (see WO-A-00/06161) as the return of a moderate or severe migraine headache within 48 hours, especially within 24 hours, of the first dosing with medication.” Applicants respectfully submit claims 32 - 37 are patentable under 35 USC 112, second paragraph, and respectfully request withdrawal of the rejection.

**Rejection under 35 USC § 103(a)**

The Examiner rejected claims 1 - 12 and 15-42 under 35 USC § 103(a) as being unpatentable over EP 436 370 (Noda, *et al.*) in view of WO 00/32589 (Dallman, *et al.*). Applicants submit that Noda *et al.* teach “...a controlled release pharmaceutical preparation which comprises (a) a core containing a pharmaceutically active substance *and an organic acid* ....” (see col. 2, l. 29 - 31 and the Examples). Applicants submit that Noda, *et al.* teach away from the instant claims which do not recite an organic acid in the core. As stated by the Examiner Noda, *et al.* do not specifically teach eletriptan as the active agent in the formulation. Applicants submit that combining Noda, *et al.* and Dallman, *et al.* in the manner suggested by the Examiner cannot produce the formulation recited by instant claims 1 - 12 and 15 - 42.

The Examiner also rejected claims 1, 2, 4 - 9, 15, 17, 18, 20 - 42 under 35 USC § 103(a) as being unpatentable over “An Organic Acid Induced Sigmoidal Release System for Oral Controlled Release Preparations” by Narisawa, *et al.* in view of WO 00/32589 (Dallman, *et al.*).

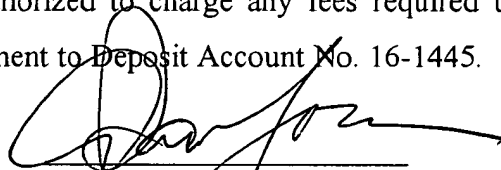
Applicants submit that the controlled release system studied by Narisawa, *et al.* contains organic acid in the drug containing core which is termed the "bead" in Narisawa, *et al.* (see page 86, 1<sup>st</sup> col., lines 8 and 9, section 2.2 Preparation of SRS and page 91, Fig. 6). Applicants submit that Narisawa, *et al.* teach away from the instant claims which do not recite an organic acid in the core. As stated by the Examiner Narisawa *et al.* do not specifically teach eletriptan as the active agent in the formulation. Applicants submit that combining Narisawa, *et al.* and Dallman, *et al.* in the manner suggested by the Examiner cannot produce the formulation recited by instant claims 1, 2, 4 - 9, 15, 17, 18, 20 - 42.

Applicants submit that claims 1 - 12, 15-42 are patentable under 35 USC § 103(a) over the cited references, either separately or in the combination cited by the Examiner, and respectfully request withdrawal of the rejection.

In view of the remarks above, the applicant respectfully submits that the pending claims are fully allowable, and solicits the issuance of a notice to such effect. If a telephone interview is deemed to be helpful to expedite the prosecution of the subject application, the Examiner is invited to contact applicant's undersigned attorney at the telephone number provided.

The Commissioner is hereby authorized to charge any fees required under 37 C.F.R. §§1.16 and 1.17 or to credit any overpayment to Deposit Account No. 16-1445.

Date: March 31, 2003



A. David Joran  
Attorney for Applicant(s)  
Reg. No. 37,858

Pfizer Inc  
Patent Department  
150 East 42nd Street - 5<sup>th</sup> Floor  
New York, NY 10017-5755  
(212) 733-3381